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EXAMINER	
PRUCHNIC, STANLEY J	

ART UNIT	PAPER NUMBER
2859	

DATE MAILED: 03/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/643,086	GLUKHOVSKY ET AL.	
	Examiner	Art Unit	
	Stanley J. Pruchnic, Jr.	2859	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-12 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/806,714.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *20041214 (3sheets)*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 1-4 and 7-10 are FINALLY objected to because of the following informalities:

- In Claim 1, Line 6, perhaps after the word "sample" the phrase --of the sensed dark current noise-- should be inserted in order to more clearly describe the invention.
- In Claim 2, it is not clear whether the integrating unit does anything with the received dark current noise samples. Perhaps the word --said-- should be inserted in line 8 in order to more clearly describe the invention, since it is considered that the change detector is operating on the same dark current noise samples received by the integrating unit.
- In Claim 3, Line 5, perhaps after the word "sample" the phrase --of the sensed dark current noise-- should be inserted in order to more clearly describe the invention.
- In Claim 3, Line 6, perhaps after the phrase "a change in temperature in vivo" the phrase --according to the dark current data sample-- should be inserted in order to more clearly describe the invention.
- In Claim 4, Line 5, perhaps after the phrase "a change in temperature in-vivo" the phrase --according to the dark current data sample-- should be inserted in order to more clearly describe the invention.
- Perhaps Claim 7 should indicate what element receives the amplified dark current noise samples in the process of communication. For consideration as to the merits, it is considered that the change detector receives the communicated amplified dark current noise samples.
- In Claim 7, in Line 1, please delete "method" and replace therefor the word --system-- in order to clearly describe the invention.

- In Claim 8, "said integrated unit" lacks antecedent basis. It is considered the "integrating unit" introduced in Claim 2.
- In Claim 9, in Line 1, please delete the word "system" and replace therefor the word -- method-- in order to clearly describe the invention.
- In Claim 10, perhaps the acronym "CMOS" should be defined in words the first time it is used.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1 and 6 are FINALLY rejected under 35 U.S.C. 103(a) as being unpatentable over **KURANISHI** (U.S. Patent No. 6,641,529 B2) in view of **LIST** (U:S. Patent No. 3,882,384 A).

KURANISHI discloses a method for sensing a temperature change in an environment, the method comprising:

introducing *in-vivo* (Col. 1, Lines 18-25) an image sensor (CCD 31) having an image sensing module (CCD 31);

KURANISHI further teaches that a sampled dark current of the image sensor introduced *in-vivo* is known to vary in dependence upon the temperature of the body into which the image sensor has been introduced (Col. 2, Lines 57-67);

sensing the dark current noise (Figs. 2-3) of the image sensing module;

obtaining a dark current data sample (and storing in memory 11; *e.g.,* sampled at time t27; stored in memory 11A) as claimed by Applicant in **Claim 1**.

KURANISHI, as described above, does not disclose comparing a dark current data sample (*e.g.,* sampled at time t27; stored in memory 11A) to a previous sample and a step of determining the temperature change in vivo according to the comparison, as claimed by Applicant in Claim 1.

LIST discloses that is known in the art to use the sampled dark current of the imager for determining temperature of the environment, the region connected thermally to the camera focal plane (Col. 5, Lines 47-50). It is very well known in the art of temperature measurement to determine changes by determining the temperature at different times.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the dark current noise provided in the image sensor introduced *in-vivo* of **KURANISHI** for determining a temperature change by sampling repeatedly and comparing the samples in order to determine the temperature change of the image sensor introduced *in-vivo* as taught by **LIST**.

OFFICIAL NOTICE is claimed regarding the displaying the in vivo temperature as claimed by Applicant in **Claim 6**, since it is very well known to display a temperature in order to provide the information to the surgeon or medical practitioner when using any type of probe in vivo. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to display the temperature changes sensed at the sensor in order to provide the information to the surgeon.

5. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over **KURANISHI** and **LIST** and further in view of **KRILL** (U. S. Patent Application Pub. No. US 2004/0122315 A1).

KURANISHI and **LIST** discloses or suggests all the limitations as claimed by Applicant in Claim 5, including the limitation that the environment of intended use is *in-vivo*.

KURANISHI and **LIST** as described above, does not teach the image sensor is contained within an autonomous *in-vivo* device.

KURANISHI and **LIST**, to summarize, is shown to teach all of the limitations as claimed by Applicant, with the exception of the image sensor being contained within an autonomous *in-vivo* device

KRILL discloses that is known in the art to provide an autonomous *in-vivo* device for carrying an imaging sensor into the body (Paras. 15 and 22).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the image sensor of **KURANISHI** and **LIST** with an autonomous *in-vivo* device for carrying the imaging sensor into the body by swallowing (ingestion; Para. 27) in order to avoid making incisions in the body as suggested by KRILL.

KRILL is evidence that ordinary workers in the field of medical diagnostics would recognize the benefit of using an ingestible autonomous *in-vivo* device as taught by KRILL for the imaging sensor of **KURANISHI** and **LIST** in order to avoid the need to make incisions for implanting the device in locations in the body.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute ingestible autonomous *in-vivo* device for the probe-type endoscope of **KURANISHI** and **LIST** in order to avoid the need to make incisions for implanting the device as taught by KRILL.

6. Claims 2 and 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over **KURANISHI** in view of **LIST.**

KURANISHI discloses a device and system for sensing a temperature change in vivo, as claimed by Applicant in Claims 2 and 7-8, comprising:

Regarding ***Claim 2:***

an image sensor 31;

an integrating unit 22;

Regarding **Claim 7**: the integrating unit amplifies said dark current noise it samples from the image sensor. There is also communication, the integrating unit including both inputs and outputs, so that information is passed through it, thus it communicates, as claimed by applicant.

Regarding **Claim 8**: the image sensor and said integrat[ing] unit 22 are controlled according to an illuminating condition, *e.g.,* Fig.2; shows "ordinary light" is extinguished during the "dark-current' data storage periods, while no light is illuminating the internal tissue (Col. 5, Line 46 through Col. 6, Line 8).

KURANISHI as described above, does not explicitly teach the functional limitation of the controller "to determine a change in temperature in-vivo".

KURANISHI, to summarize, is shown to teach all of the limitations as claimed by Applicant in claims 4, 11 and 12, with the exception of the use of the dark current data sample "to determine a change in temperature".

LIST discloses that is known in the art to use the sampled dark current of the imager for determining temperature of the environment, the region connected thermally to the camera focal plane (Col. 5, Lines 47-50). It is very well known in the art of temperature measurement to determine changes by determining the temperature at different times.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the dark current noise provided in the image sensor introduced *in-vivo* of **KURANISHI** for determining a temperature change by sampling repeatedly and comparing the samples in order to determine the temperature change of the image sensor introduced *in-vivo* as taught by **LIST**.

7. Claims 4 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over **KURANISHI** in view of **LIST.**

KURANISHI discloses a device for sensing a temperature change in vivo, as claimed by Applicant in Claims 4 and 11-12, comprising:

Regarding Claim 4:

an image sensor 31;

a controller (observation-mode changeover switch 21 in combination with the secondary circuit 1) which causes a dark current noise of the image sensor to be obtained, sampled (stored in memory 11; Fig. 1) as claimed by Applicant in Claim 4.

Regarding **Claim 11**: the image sensor senses the dark current noise during a dark period (Fig. 3).

Regarding **Claim 12**: the image sensor communicates with said controller during periods when said image sensor is not illuminated (Fig.2; shows "ordinary light" is extinguished during the "dark-current' data storage periods).

KURANISHI as described above, does not explicitly teach the functional limitation of the controller "to determine a change in temperature in-vivo".

KURANISHI, to summarize, is shown to teach all of the limitations as claimed by Applicant in claims 4, 11 and 12, with the exception of the use of the dark current data sample "to determine a change in temperature".

LIST discloses that is known in the art to use the sampled dark current of the imager for determining temperature of the environment, the region connected thermally to the camera focal plane (Col. 5, Lines 47-50). It is very well known in the art of temperature measurement to determine changes by determining the temperature at different times.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the dark current noise provided in the image sensor introduced *in-vivo* of **KURANISHI** for determining a temperature change by sampling repeatedly and comparing the samples in order to determine the temperature change of the image sensor introduced *in-vivo* as taught by **LIST**.

8. Claims 3, 9 and 10 are FINALLY rejected under 35 U.S.C. 103(a) as being unpatentable over **LIST** in view of **KRILL**.

LIST discloses a method for sensing a temperature change in an environment, the method comprising:

sensing dark current of an image sensor (and regarding **Claim 10**, comprising CMOS) for determining temperature of the environment, the region connected thermally to the imager focal plane (Col. 5, Lines 47-50). Moreover, it is very well known in the art of temperature measurement to determine changes by determining the temperature at different times, but LIST discloses determining temperature changes (Col 6, Lines 58), including temperature differences.

LIST further discloses obtaining a dark current data sample and determining temperature from the dark current data sample. Any time the comparator, for example, is used for sensing dark current differences, data is sampled, since it is not sensed continuously.

LIST, to summarize, is shown to teach or suggest all of the limitations as claimed by Applicant in **Claims 3 and 10**, with the exception of introducing *in-vivo* the image sensor, and thus, measuring a temperature change in vivo. Also LIST does not describe the method or system wherein the image sensor is contained within an autonomous in vivo device, as claimed by Applicant in **Claim 9**.

KRILL discloses that is known in the art to provide an autonomous *in-vivo* device for carrying an imaging sensor into the body (Paras. 15 and 22).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the image sensor of **KURANISHI** and **LIST** with an autonomous *in-vivo* device for containing the imaging sensor (Para. 27) in order to measure the temperature while obtaining *in-vivo* images for diagnosis of a medical condition of a living body as suggested by KRILL.

KRILL is evidence that ordinary workers in the field of medical diagnostics would recognize the benefit of using an ingestible autonomous *in-vivo* device as taught by

KRILL for holding the imaging sensor of **LIST** in order to avoid the need to make incisions for implanting the device in locations in the body.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute ingestible autonomous *in-vivo* device for the probe-type endoscope of **LIST** in order to measure the temperature while obtaining *in-vivo* images for diagnosis of a medical condition of a living body as suggested by KRILL.

Response to Arguments

9. Applicant's arguments, see the response, filed 27 December 2004, with respect to the rejections of record have been fully considered and are persuasive in view of the amendments to Claims 1-4. The rejections of the previous Office Action have been withdrawn.

10. In support of Applicant's arguments, see the attached Interview Summary of the telephonic interview held 14 December 2004. It was prepared by the Examiner and signed by the Primary Examiner on 14 December 2004, but an administrative problem prevented it from being mailed earlier.

11. In the interview, the Examiners agreed with Applicant that limiting the system and method to the use of an image sensor "*in vivo*", as has been done in each of the independent claims, rather than more broadly "introducing [the image sensor] into an environment" appeared to overcome the rejections of record.

12. Applicant's further arguments with respect to claims 1-4 have been considered but are moot in view of the new ground(s) of rejection. However, the argument(s), *i.e.*, that the references do not "**calculate or determine a temperature change... according to dark current samples**", will be addressed as applied to the amended claims.

13. As applied to **Claims 1-4**: In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the

features upon which applicant relies (*i.e.,* to "**calculate ... a temperature change...according to dark current samples**") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). None of the claims require a temperature change to be **calculated** according to dark current samples. Each of the independent claims is directed to one of a method, device or system "for **sensing** a temperature change *in vivo*", and in the body of the claim, the claims recite the functional language "**for determining**" or "**to determine**" "a temperature change...". The terms sensing and determining do not require any calculation steps or functions. Nor do these terms require any measurements or numerical output. Broadly interpreted, the function of "determining a temperature change" only requires sensing that said temperature change has occurred.

14. Moreover, regarding **Claims 3-4**: In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (*i.e.,* to "**calculate or determine a temperature change... according to dark current samples**") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). **Claims 3-4** do not require the temperature change to be determined according to dark current samples. In Claims 3-4, the dark current data samples are not claimed to have a relationship to the determined "change in temperature *in-vivo*".

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The prior art cited in the PTO-892 and not mentioned above disclose related temperature measurement and imaging devices and methods.

IDDAN et al. (U.S. Pat. No. 5,604,531 and also US 20010035902 A1 (Iddan, Gavriel J: et al.) having a common assignee as the instant application), discloses a swallowable autonomous endoscope having a CCD imager, but no sensing of temperature from the dark current noise is disclosed. Moreover, IDDAN teaches (*e.g.,* see Paragraph 48, in US 2001/0035902) the CMOS imaging chip is preferred to have a small dark current response as a function of temperature.

SATO et al. U.S. Pat. No. 4,646,724) discloses an endoscopic CCD camera, but does not measure dark current, and teaches away from sensing dark current or integrating during the dark period (Col. 7, Lines 51-52).

US 5278656 A (Hynecek; Jaroslav et al.) discloses an endoscope apparatus including a CCD imager and teaches reading out the image data (communicating with a controller) during periods when said image sensor is not illuminated (Figs. 8b, 8c).

US 6641529 B2 (Kuranishi; Hideaki) discloses an endoscope including dark-current correction wherein dark current is sensed by an imager (CCD31) during a dark period, while no light is illuminating the internal tissue (Col. 5, Line 46 through Col. 6, Line 8).

US 20040099920 A1 (Rossi, Giuseppe et al.; and a previously cited publication by the same inventors) discloses a method for determining temperature of an active pixel imager using the dark current sampled from the imager. ROSSI is not prior art, but shares features in common with Applicant's invention.

The remaining U. S. Patent documents disclose related devices or methods. *e.g.,* KRYMSKI discloses an Active Pixel Sensor (CMOS) having temperature dependent "KTC" noise. MINEMIER discloses dark current noise compensation in an imager using an embedded silicon diode in the same integrated circuit with the image sensor. Also includes teachings on use of shutter to provide dark frames.

Regarding use of dark current for measuring temperature: In the first Office Action, mailed 24 September 2004, three non-patent literature references were cited in order to provide background relating to the state of the art use of ***thermal or Johnson noise*** for measurement of temperature:

- Jones, B.K., "Electrical Noise Thermometer," Appl. Phys. vol. 16, No. 1, pp. 99-102 (May 1978).
- Holst G.C.,"CCD arrays cameras and displays", Second Edition (SPIE O.E. Press and JCD Publ.), chap. 4. pp. 102-145 (1998, no month).
- Ritter, T., "Random Electrical Noise: A Literature Survey, Research Comments from Ciphers By Ritter," www.io.com, (Dec 1999).

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stanley J. Pruchnic, Jr., whose telephone number is **(571) 272-2248**. The examiner can normally be reached on weekdays (Monday through Friday) from 7:30 AM to 4:00 PM . If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diego F. F. Gutierrez can be reached at **(571) 272-2245**.

The *Official FAX* number for Technology Center 2800 is (703) 872-9306 for *all official communications*.

Any inquiry of a general nature or relating to the status of this application or proceeding may be directed to the official USPTO website at **http://www.uspto.gov/** or

you may call the **USPTO Call Center** at **800-786-9199** or 703-308-4357. The Technology Center 2800 Customer Service FAX phone number is (703) 872-9317.

The cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources.

Private PAIR provides external customers Internet-based access to patent application status and history information as well as the ability to view the scanned images of each customer's own application file folder(s).

For inquiries relating to Patent e-business products and service applications, you may call the *Patent Electronic Business Center (EBC)* at 703-305-3028 or toll free at 866-217-9197 between the hours of 6 a.m. and midnight Monday through Friday EST, or by e-mail at: **ebc@uspto.gov**. Additional information is available on the Patent EBC Web site at: **http://www.uspto.gov/ebc/index.html**.

GAIL VERBITSKY
PRIMARY EXAMINER

SJP

Stanley J. Pruchnic, Jr.
23 March 2005